

### REMARKS

This responds to the Office Action mailed on December 12, 2005, and the references cited therewith.

No claims are amended.

#### §112 Rejection of the Claims

Claims 19-22, 24 and 34-42 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants respectfully point out that whereas these claims are stated to be rejected under the written description requirement of 35 U.S.C. §112 paragraph 1, the Examiner also states (page 5 of the Office Action) that the claims are indefinite. An assertion that a claim is indefinite is properly made under 35 U.S.C. §112 paragraph 2 when an Applicant allegedly fails to “particularly point out and distinctly claim” an invention. *In re Borkowski*, 422 F.2d 904 (CCPA 1970). However, the Examiner does not appear to assert a rejection on the basis of §112 paragraph 2 in the present Office Action. Thus, Applicants can only assume that the Examiner’s statement that the claims are indefinite is meant to support his assertion that the application fails to meet the written description requirement of §112 paragraph 1. Therefore, Applicants traverse and request withdrawal of the rejection under §112 paragraph 1 as stated by the Examiner, and provide arguments herein in support of this traverse. Applicants do not address any possible rejection under §112 paragraph 2, as such is believed not to have been stated. If Applicants are mistaken in this, clarification by the Examiner is requested.

The Examiner refers to “claim 1” on page 4 of the Office Action. It is believed that this is a typographical error, and that the Examiner is referring to claim 19, the single independent claim of the application. The rejection is thus addressed in reference to claim 19. The claim element that the Examiner has indicated is problematic is the phrase “free of a plasticizer” found in claim 19, which the Examiner asserts has an unreasonable degree of uncertainty.

However, that claim element is described in the Specification as written in such full, clear, concise and exact terms as to enable a person skilled in the art to make and use the invention. Definitions and examples of “a plasticizer” are described in the Specification. On page 14, the Specification discloses that the release profile of the drug may be modified by

“crosslinking or plasticizing.” In the next sentence the Applicants further disclose that “[c]rosslinking agents known in the art . . . may include glyoxal, propylene glycol, glycerol . . .”. The Examiner admits that on page 15 of the specification it is disclosed that a “[s]uitable excipient or plasticizer . . . may include alkyl-glycol such as propylene glycol, polyethyleneglycols . . . “. The statement on page 14 that drug release profiles may be altered by “crosslinking or plasticizing” is in no way contradicted by the examples of crosslinking agents cited in the next sentence, or the examples of plasticizers provided on page 15. There is no inconsistency between these statements, or uncertainty generated by them, as it is well-known in the art that a given chemical compound (e.g. propylene glycol) may fulfill both roles. For example, propylene glycol may function both as a crosslinker as stated on page 14 and as a plasticizer as stated on page 15. One manner in which propylene glycol could function as a crosslinker is through formation of covalent bonds between polymer molecules and the two hydroxyl groups of the propylene glycol molecule, for instance by formation of ester, hemiacetal, acetal, ketal, or ether bonds, or Michael adducts. One manner in which propylene glycol could function as a plasticizer is by dissolving in the polymer mass and altering its physical properties.

Applicants thus respectfully assert that they have described the invention in full, clear, concise and exact terms. Accordingly, Applicants respectfully request withdrawal of the rejection.

#### §102 Rejection of the Claims

Claims 19-22, 24 and 34-40 were rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 4,765,983 to Takayanagi et al.

The Applicants traverse this rejection and request withdrawal of the rejection.

For a valid rejection under section §102, every limitation of a rejected claim must identically appear in a single prior art reference. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d (BNA) 1566, 1567 (Fed. Cir. 1990). Implicit in such a determination is that the claim must have first been correctly construed to define its scope and meaning. *Gechter v. Davidson*, 43 U.S.P.Q.2d 1030, 1032 (Fed. Cir. 1997). Anticipation requires that each and every element of the rejected claim, once properly construed, be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 U.S.P.Q.2d (BNA) 1655 (Fed. Cir. 1990). Each element of the rejected

claim must either be inherent or disclosed expressly in the reference and must be arranged therein as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 U.S.P.Q.2d (BNA) 1913 (Fed. Cir. 1989).

The cited Takayanagi document fails to disclose every element of claim 19 either literally or through equivalents (MPEP 904.01(b)). Claim 19 recites “a first water-erodible adhesive layer that is free of a plasticizer, and a second water-erodible non-adhesive backing layer that comprises hydroxyethyl cellulose.” Thus, claim 19 recites that both layers are water-erodible.

In contrast, the cited document makes clear that in the adhesive medical tape it discloses, the backing layer is NOT water-soluble or water-erodible. For example, it is stated (column 3, lines 50-68) that “[t]he support layer composed of such an intestine-soluble polymer functions to prevent the form of the adhesive medical tape from being collapse or deformed . . . the dissolution of such a portion scarcely occurs (i.e., the useless dissolution is very small).” The “intestine soluble” support layer, which backs the medicament-containing soluble layer, thus is not water-erodible. The medicament-containing soluble layer is stated (column 2, lines 58-61) as being a “water-soluble polymer” that is “capable of dissolving mainly in the oral cavity or stomach.” The backing layer of Takayanagi that is stated to dissolve in the intestine is clearly indicated to be swallowed by the patient after the water-soluble medicament-containing layer has dissolved, such that it may reach the intestine to be dissolved. In contrast, the backing layer of the instant claim 19 is indicated to dissolve in the mouth such that no solid material from the pharmaceutical carrier device of the present invention is swallowed by the patient. Accordingly, that claim element of the instant claim 19 is not found in the disclosure of Takayanagi.

It is thus shown that the disclosure of Takayanagi cannot properly be asserted to anticipate claim 19 (or any of the other claims, all of which are dependent directly or indirectly on claim 19). Applicants request that the rejection be withdrawn and the claims be allowed.

### §103 Rejection of the Claims

Claims 19-22, 24 and 34-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 4,765,983 to Takayanagi et al. in view of US Patent No. 4,594,240 to Kawata et al.

The Applicants traverse this rejection and request withdrawal of the rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations of the rejected claim. Second, there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to person of ordinary skill in the art to modify the references or combine reference teachings so as to arrive at the claimed invention. Third, the art must provide a person of ordinary skill with a reasonable expectation of success. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure (M.P.E.P. § 2143, citing with favor *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

As discussed above, Takayanagi does not disclose the claim element of the instant claim 19 of a water-erodible backing layer. The corresponding layer disclosed by Takayanagi is specifically stated NOT to be water-soluble, but is swallowed in solid form so it may reach the intestine where it is stated to dissolve.

Neither does the cited document of Kawata disclose a water-soluble backing layer or its equivalent. Kawata's sheet-shape adhesive preparation comprises a sheet-like layer of a pharmaceutical composition and a base sheet. The base sheet, corresponding to the backing layer of the instant claim 19, is disclosed (column 2, lines 25-31) to be made from water-insoluble materials such as nylon, papers, polyvinylchloride film and other materials well-known in the art NOT to be water-soluble. Indeed, Kawata states (column 2, lines 29-31) that "[m]aterials having poor water resistance such as paper may be coated with a protecting coating layer." Thus, Kawata explicitly teaches away from the invention of the instant claim 19, such that a motivation is provided to make the base or backing sheet less water-soluble, not more.

Therefore, Kawata does not disclose a water-erodible layer as is recited in the instant claim 19. Neither cited document offers any suggestion or motivation to a person of ordinary skill to modify the water-insoluble backing layer of the cited documents to a water-soluble backing layer of the present application; indeed, a water-soluble backing layer is explicitly taught away from in the cited documents.

Based on this, claim 19 cannot be obvious over the cited documents. A *prima facie* case of obviousness has not properly been made by the Examiner, so the Applicant need not rebut an assertion of obviousness.

Applicants respectfully request withdrawal of the rejection and allowance of the claims as presented.

Double Patenting Rejection

Claims 19-22, 24 and 34-42 were rejected under a non-statutory double patenting rejection over claims 1-27 of U.S. Patent No. 6,159,498. Applicant does not admit that the claims are obvious in view of U.S. Patent No. 6,159,498. However, a Terminal Disclaimer in compliance with 37 C.F.R. 1.321(b)(iv) is enclosed herewith to obviate these rejections.

Claims 19-22, 24 and 34-42 were rejected on the ground of nonstatutory double patenting over claim 1 of U.S. Patent No. 5,800,832 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Applicant does not admit that the claims are obvious in view of U.S. Patent No. 5,800,832. However, a Terminal Disclaimer in compliance with 37 C.F.R. 1.321(b)(iv) is enclosed herewith to obviate these rejections.

Claims 19-22, 24 and 34-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 15-18 and 33-34 of copending Application No. 09/069,703. Applicant respectfully traverses this rejection, in that the cited application has not yet matured into a patent. To the extent that the rejection is maintained if the cited application becomes the first-allowed patent of the two, Applicant will provide an appropriate Terminal Disclaimer in the present application at that time.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date

April 11, 2006

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11 day of April, 2006.

Name

Signature